

New England Compounding Center –
Compounding Pharmacy Inspection Report: dated—2/20/2004

5) Computer Software Name PK (PCCA) Support Number 800 331 2418

6) Label Compliance

Legend label compliant with interchange

7) Written copy of Policy & Procedures Manual on location related to the handling of Medication Errors

Y N NA

Y N

O.B.R.A

1) Counseling Sign (11" x 14") posted:

2) Designated Confidential Counseling Area

3) Drive Up Window: Y N Sign Posted: Y

4) Counseling offer is offered by: Pharmacist Reg. Tech. N Certified Tech N
Intern / Student / Grad. Pharmacist?

5) Record maintained of Offer to Counsel

6) Monographs used?: All prescriptions

New prescriptions only

7) Prospective DUR on new prescriptions?

Conducted by:

Pharmacists?

Certified Tech?

Reg. Tech?

Intern / Student / Grad. Pharmacist

Y N

Y N

E.D.T.

1) Random Sampling of Purported Prescriptions: DEA # Correct

2) Identifier of Recipient on Rx.

3) Transmitting by Computer on time? Disc

4) Counseling or Intervention Book - in computer folder

5) Patient Drug Regimen Review completed prior to dispensing medication.

Y N

Y N

Y N

Y N

Y N

RECORD KEEPING

1) Biennial Inventory Readily Retrievable

Date of last inventory: 9/11/03

2) Date of Last Change of Manager NA

3) 222 Forms Sampling Compliant

4) Power of Attorney on File

Located where:

5) Perpetual Inventory Schedule II Y N

Date Last Reconciled: 9/7 days

Date of Inspection: 8/10/04

6) Schedule III through Schedule IV controlled substances dispersed through the pharmacy?

7) Controlled substances in Schedule II locked and stored in the pharmacy

8) Controlled substance deliveries are delivered directly to the pharmacy dept.

9) Biennial Inventory readily retrievable?

Last Inventory date: 9/11/03

10) Inventory taken for Change of pharmacy manager

Date taken NA

Name of Incoming pharmacist

Name of Outgoing pharmacist

11) Procedures in practice to validate controlled substance prescription

12) Computerized records of distribution by schedule

a) Signed daily by pharmacist

b) Central Record Keeping Authority

13) Schedule II prescriptions are segregated

14) Schedule III, IV, and V prescriptions maintained in a separate file

15) Schedule VI prescriptions and syringes and instruments filed together

Y N

NA

Y N

Y N

Y N

Y N

Y N

Y N

Y N

Y N

Y N

Y N

Y N

HPP Training
2 Backlog

CODE OF PROFESSIONAL CONDUCT - 247 CMR 9.01

- 1) Patient Confidentiality ☒ Y ☐ N
- 2) Corresponding Responsibility: making sure prescription is for a legitimate use in usual course of practice. ☒ Y ☐ N
- 3) Doctor Shoppers as it relates to OBRA ☒ Y ☐ N
- 4) Faxing of Prescriptions ☒ Y ☐ N
 - a) plain paper fax
 - b) location of fax: Pharmacy
 - c) accept Schedule II fax prescriptions for reference? ☒ Y ☐ N
- 5) Prescribers signature is on face of prescription faxed ☒ Y ☐ N
- 6) Faxed prescription or drug order is marked Electronically Transmitted RX ☒ Y ☐ N
- 7) Fax includes the identification number of the sending facsimile machine ☒ Y ☐ N
- 8) Record maintained for transferring prescriptions ☒ Y ☐ N
 - Computerized record: ☒ Y ☐ N Hard copy log ☒ Y ☐ N
- 9) Emergency authorized prescriptions in Schedule II accepted? ☒ Y ☐ N
 - a) Marked for authorization for emergency dispensing i.e. faxes: marked with both: Electronically transmitted RX and Authorization for Emergency Dispensing ☒ Y ☐ N
 - b) Written prescription is postmarked with in 7 days to pharmacy ☒ Y ☐ N
 - c) Non-compliant physicians reported to DPH and DEA? ☒ Y ☐ N
- 10) Copies of pharmacists license posted ☒ Y ☐ N
- Copies of technicians licenses posted ☒ Y ☐ N
- 11) Names badges and titles noted ☒ Y ☐ N
- 12) Manager of record is responsible for (setting forth) policy & procedures ☒ Y ☐ N
 - a) staff is adequately trained ☒ Y ☐ N
 - b) technician manual on premises ☒ Y ☐ N
 - c) ratio pharmacists to technicians 4 : 1
- 13) Number of Students/ Interns 1 Reg. Pharm. techs 1 Cert. Pharm. techs 1
Pharmacists 1
- 14) After hours access to pharmacy? ☒ Y ☐ N
- 15) Evidence of security cameras ☒ Y ☐ N
- 16) Quarantine area for control substances in schedule II, III, IV, V recalls or expired product segregated from current inventory ☒ Y ☐ N *boxed as quar*
- 17) Quarantine area for schedule VI expired or recalled items ☒ Y ☐ N
- 18) Biohazard waste appropriately flagged ☒ Y ☐ N
- 19) Name of Reverse Distributor Clan Ventures telephone number 508 872 8000
date of last return: 11/1/04
- 20) JCAHO approved? ☒ Y ☐ N
- 21) Log noting re-packaging date, expiration date, lot number, manufacturer, expiration date, size of packages, filled by and checked by? ☒ Y ☐ N
- 22) Current file of patients requesting Non Child Proof Caps? (NCPC) and is a release on file? ☒ Y ☐ N *computerized*
- 23) Repackaged unit dose log complete (Date, manufacturer, manuf. exp. date, lot number, quantity, tech prep, internal lot number, R.Ph verified and initialed) ☒ Y ☐ N *NA*
- 24) Refrigerator cleanliness ☒ Y ☐ N
 - a) Temperature log ☒ Y ☐ N
 - Freezer log ☒ Y ☐ N
 - Freezer free of frost buildup ☒ Y ☐ N
 - b) Thermometer present? Temperature 39° ☒ Y ☐ N
 - c) Biological Refrigerator ☒ Y ☐ N
 - d) Employee Refrigerator ☒ Y ☐ N

- 25) Technician Training Manual on site
 Last update 2/04 last in-service 2/17/04 ☒ Y ☐ N
- 26) Pharmacy and dispensing are, clean, organized, neat, adequate ☒ Y ☐ N
- 27) After hours access to pharmacy?
 Answering service In house Telephone Number _____ ☒ Y ☐ N

CIVAS PHARMACY (Central Intravenous Admixture Service) / Compounding Information:

- 1) Clean room minimum of 72 sq. ft ☒ Y ☐ N
- 2) Clean room adjacent to prescription department ☒ Y ☐ N
- 3) Room under continual positive pressure ☒ Y ☐ N Hood only
- 4) CIVAS letter from Board posted
 date of letter 5/99 ☒ Y ☐ N
- 5) Adequate Reference Standards ☒ Y ☐ N
- 6) Sterile Products: Laminar Flow Hood (name) Microsphere Expiration date _____
 Vertical Flow Hood (name) _____ Expiration date _____
 Serviced by: Scientific Air Analy telephone # 800-287-5252 exp. 8/31/04
- 7) Written Quality Assurance Guidelines to include aseptic technique, sterility, stability and endotoxins testing? ☒ Y ☐ N
- 8) Pharmacy will test and sterilize vials and stoppers for sterile products? Received ☒ Y ☐ N
- 9) Adequate Education in Sterile Products Last update 4 Last in-service 1/04
- 10) Batch log is initialed or signed by technician preparing the compound? ☒ Y ☐ N Non-sterile only
- 11) Quality controls in place ☒ Y ☐ N
- 12) Log for such controls in place?
 a) Air Quality ☒ Y ☐ N
 b) Filters ☒ Y ☐ N
 c) Floors and Equipment cleaned ☒ Y ☐ N
 d) IV room and AnteRoom clean ☒ Y ☐ N PCCA
- 13) Computer Software Name PK Software Support Number 1-800-331-2498
 Label Compliance: Compounding label: ☒ Y ☐ NA
 IV label ☒ Y ☐ NA
- 14) All prescriptions are patient specific ☒ Y ☐ N
- 15) Compounding practices are in conformance with U.S. FDA guidelines ☒ Y ☐ N
- 16) All bulk compounding materials will be purchased from a U.S. Food and Drug approved manufacturer ☒ Y ☐ N
- 17) Certificates of analysis will remain filed on site and be readily retrievable ☒ Y ☐ N
- 18) Policy exists for how beyond use dates will be determined ☒ Y ☐ N
- 19) Batch log sheets will be kept on all compounded prescriptions compounded to include product name, expiration dates, manufacturers lot numbers, pharmacy lot numbers, name of patient / rx number, who calculated, who compounded, who verified the prescription. ☒ Y ☐ N
- 20) Pharmacy will advertise the business as a compounder and not the specific products? ☒ Y ☐ N

SUPPLIER INFORMATION

- 1) PCCA 2) Spectrace 3) _____

PHARMACIST ROSTER (List or see attach Roster)

- 1) Lisa Cadogan
 2) Barry Cadogan
 3) _____
 4) _____
 5) _____

Registered Technicians ROSTER (List or see attached Roster)

- 1) _____
- 2) _____
- 3) _____
- 4) _____
- 5) _____

Inspection Findings

- 1) complaint on all concerns as addressed
- 2) in complaint
- 3) _____

PHARMACIST INTERVIEWED

Signature [Signature] License Number 21239 Date 2/20/04

Investigator Assigned [Signature]

Statutes / Regulations Cited:

A = 21 USC

B = 247 CMR

C = 105 CMR D = 94CL

E = MGL 112 SEC 61

F = MGL C138 S 15L G = MGL C 138 S 30 A